

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Benylin Phlegm Cough Menthol 100mg/5ml Oral Solution

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

This product contains 20 mg guaifenesin in each ml (100mg in 5ml).

Excipient(s) with known effect (mg per ml):

- Ethanol 39.7mg
- Ponceau 4R (E124) 0.05mg
- Sodium 1.8mg
- Glucose
- Fructose

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

- Oral solution
- Clear to slightly opalescent red liquid

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic Indications

Benylin Phlegm Cough Menthol is indicated to help loosen phlegm and thin bronchial secretions associated with productive cough, for use in adults and adolescents over 12 years.

### 4.2 Posology and method of administration

#### Posology

#### Adults and adolescents over 12 years:

For oral administration: 10 ml (200mg guaifenesin) 4 times a day.  
Maximum daily dose: 40ml (800mg guaifenesin)

#### Children under 12 years:

Not recommended.

#### The Elderly:

As per adults.

#### Hepatic/renal impairment

Caution should be exercised in severe hepatic and severe renal impairment.

If cough persists for more than 7 days, tends to recur, or is accompanied by a fever, rash, or persistent headache, a physician should be consulted.

#### Method of administration:

## Oral

### **4.3 Contraindications**

Hypersensitivity to active substance or to any of the excipients listed in section 6.1.

### **4.4 Special warnings and precautions for use**

This product should not be used for persistent or chronic cough, such as occurs with asthma, or where cough is accompanied by excessive secretions, unless directed by a physician.

A persistent cough may be a sign of a serious condition. If cough persists for more than 7 days, tends to recur, or is accompanied by a fever, rash, or persistent headache, a physician should be consulted.

Caution should be exercised when using the product in the presence of severe renal or severe hepatic impairment.

The concomitant use of cough suppressants is not recommended.

Patients with rare hereditary problems of fructose intolerance or glucose galactose malabsorption should not take this medicine.

This product contains 4.7 vol % ethanol (alcohol), i.e. up to 400 mg per dose, equivalent to approximately 10 ml beer, 4 ml wine per 10 ml dose. This can be harmful for those suffering from alcoholism. The ethanol content should be taken into account in pregnant or breast-feeding women, children and high-risk groups such as patients with liver or kidney disease or epilepsy.

This product contains Ponceau 4R (E124) red colouring which may cause allergic reactions.

This product contains 17.6mg sodium per 10ml dose. This should be taken into consideration by those on a controlled sodium diet.

### **4.5 Interaction with other medicinal products and other forms of interaction**

If urine is collected within 24 hours of a dose of this product a metabolite of guaifenesin may cause a colour interference with laboratory determinations of urinary 5-hydroxyindoleacetic acid (5-HIAA) and vanillylmandelic acid (VMA).

Expectorants such as guaifenesin should not be combined with cough suppressants in the treatment of cough since the combination is illogical and patients may be exposed to unnecessary adverse effects.

No interaction studies have been performed which revealed an interaction with guaifenesin.

### **4.6 Fertility, pregnancy and lactation**

#### **Pregnancy**

There are no or limited amount of data from the use of guaifenesin in pregnant women. Animal studies are insufficient with respect to reproductive toxicity (see section 5.3). Benylin Phlegm Cough Menthol is not recommended during pregnancy and in women of childbearing potential not using contraception

#### **Breast feeding**

Guaifenesin is excreted in breast milk in small amounts. There is insufficient information on the effects of Guaifenesin in newborns/infants. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from Benylin Phlegm Cough Menthol 100 mg/ 5 ml Oral Solution therapy, taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman.

#### **Fertility**

There is insufficient information available to determine whether guaifenesin has the potential to impair fertility.

## 4.7 Effects on ability to drive and use machines

Guaifenesin has no or negligible influence on the ability to drive and use machines..

## 4.8 Undesirable effects

The following side effects may be associated with the use of guaifenesin:

Immune System Disorders: Hypersensitivity reactions including pruritus and urticaria, rash (frequency – not known).

Gastrointestinal disorders: Abdominal pain upper, diarrhoea, , nausea, vomiting (frequency – not known).

### Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); e-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie)

## 4.9 Overdose

### Symptoms and signs

The symptoms and signs of overdose may include gastro-intestinal discomfort, nausea and drowsiness.

When taken in excess, guaifenesin may cause renal calculi.

### Management

Treatment should be symptomatic and supportive.

## 5 PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

Pharmacotherapeutic Group: Cough and Cold Preparations, Expectorants ATC Code: R05CA03

Mechanism of action:

Guaifenesin is thought to exert its pharmacological action by stimulating receptors in the gastric mucosa. This increases the output from secretory glands of the gastrointestinal system and reflexly increases the flow of fluids from glands lining the respiratory tract. The result is an increase in volume and decrease in viscosity of bronchial secretions. Other actions may include stimulating vagal nerve endings in bronchial secretory glands and stimulating certain centres in the brain, which in turn enhance respiratory fluid flow. Guaifenesin produces its expectorant action within 24 hours.

### 5.2 Pharmacokinetic properties

There is no information available on the pharmacokinetics of guaifenesin in special populations.

### Absorption

Guaifenesin is well absorbed from the gastro-intestinal tract following oral administration, although limited information is available on its pharmacokinetics. After the administration of 600 mg guaifenesin to healthy adult volunteers, the  $C_{max}$  was approximately 1.4 ug/ml, with  $t_{max}$  occurring approximately 15 minutes after drug administration.

**Distribution**

No information is available on the distribution of guaifenesin in humans.

**Biotransformation and elimination**

Guaifenesin appears to undergo both oxidation and demethylation. Following an oral dose of 600 mg guaifenesin to 3 healthy male volunteers, the  $t_{1/2}$  was approximately 1 hour and the drug was not detectable in the blood after approximately 8 hours.

**5.3 Preclinical safety data****Carcinogenicity**

There is insufficient information available to determine whether guaifenesin has carcinogenic potential.

**Mutagenicity**

There is insufficient information available to determine whether guaifenesin has mutagenic potential.

**Teratogenicity**

There is insufficient information available to determine whether guaifenesin has teratogenic potential.

**Fertility**

There is insufficient information available to determine whether guaifenesin has the potential to impair fertility.

**6 PHARMACEUTICAL PARTICULARS****6.1 List of excipients**

Xanthan gum  
Sodium chloride  
Saccharin sodium  
Ammonium glycyrrhizate  
Sodium benzoate (E211)  
Citric acid anhydrous  
Sodium citrate  
Macrogol glycerol hydroxystearate 40  
Levomenthol  
Raspberry flavour F2126 (includes ethanol, glucose and fructose)  
Caramel (E150) (includes glucose)  
Ponceau 4R (E124)  
Glycerol  
Macrogol 1500  
Propylene glycol  
Ethanol 96%  
Purified water

**6.2 Incompatibilities**

Not applicable.

### **6.3 Shelf life**

3 years  
In-use: 4 weeks

### **6.4 Special precautions for storage**

Do not store above 25°C  
Store in the original container to protect from light

### **6.5 Nature and contents of container**

Type III, Amber glass bottle, containing 150ml, fitted with:

A plastic child resistant cap fitted with a PET-faced wad.

A plastic dosing cup marked with a 10ml graduation is included in this pack

### **6.6 Special precautions for disposal**

No special requirements.

Any unused medicinal product should be disposed of in accordance with local requirements)..

## **7 MARKETING AUTHORISATION HOLDER**

Mc Neil Healthcare (Ireland) Ltd,  
Airton Road,  
Tallaght,  
Dublin 24,  
Ireland

## **8 MARKETING AUTHORISATION NUMBER**

PA0823/066/001

## **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of First Authorisation: 7th October 2011

## **10 DATE OF REVISION OF THE TEXT**

April 2017